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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,016	02/09/2001	Patrick J. Muraca	5568/1020	6417
29932	7590	05/20/2005	EXAMINER	
PALMER & DODGE, LLP PAULA CAMPBELL EVANS 111 HUNTINGTON AVENUE BOSTON, MA 02199			CLOW, LORI A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/781,016	<b>Applicant(s)</b> MURACA, PATRICK J.	
	<b>Examiner</b> Lori A. Clow, Ph.D.	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-75 is/are pending in the application.  
     4a) Of the above claim(s) 47-50 and 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 6-46 and 51-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' arguments, filed 9 December 2004, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 6-75 are currently pending. Claims 6-46 and 51-74 are being examined on the merits. This application contains claims 47-50 and 75 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 47-50 and 75 remain withdrawn.

### **Specification**

The use of the trademarks SNOMED® and Spotfire™ have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. See page 18, line 15. Correction is requested.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34 and 44 contains the trademark/trade names SNOMED® and Spotfire™.

Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a specific type of computer code and, accordingly, the identification/description is indefinite.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-17, 19-33, 37-42, 45, 46, and 51-74 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,847,897 B1 (Bassett et al.). *This is a new grounds of rejection necessitated by the amendments to the claims.*

In reference to claims 6,19, 24, 37, 42, 46, 51-57, 59, 60, 62, 64, and 71 Bassett et al. teach a “system, method, and computer program product for improved computer-aided analysis

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of biological data derived from machine readable outputs of experiments performed on a plurality of biological samples (column 1, lines 66 and 67 to column 2, lines 1-2)". In Figure 3, Bassett et al. describe a biological database software 302 which comprises a communications interface module 308, a biological information processing module 310, a database 312, and a SQL query processing/response module 314. Communications interface module 308 coordinates data transfer between the database server 106 and the scanning device 104 for receiving biological response information (column 14, lines 61-67 to column 17, lines 64). Samples may consist of biological data from any multicellular organism (claim 37) (column 10, lines 31-34).

In regard to the "database searching function allowing the user to design queries, Bassett et al. teach "biological menu and submenu items that are displayed to the user during searches, projections, and the like are not stored in the user computer, rather are stored in a central response database", thus meeting the limitation of querying information (column 2, lines 26-34).

In regard to "the relationship determination function", Bassett et al. teach "computing a correlation metric between at least one of said plurality of biological signal profiles and other of said plurality of biological signal profiles in a central database server" (column 5, lines 9-12).

In regard to claim 7, which identifies sublocation, Bassett et al. disclose "a subset of biological data" at column 2, line 63.

In regard to claim 8, Bassett et al. teach "projecting said source dataset onto a destination viewer that corresponds to said source data from a source viewer, said destination viewer being a different one of said plurality of viewers than said source viewer; whereby user observation of biological relationships that may exist in said samples may be enhanced through the facilitated viewing of said source dataset as projected onto said destination viewer (column 3, lines 3-10)".

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In regard to claims 9, 10, 13, 43, 58, and 72, Bassett et al. teach a computer systems comprising links (column 31, lines 2-13).

In regard to claims 11 and 12, Bassett et al. describe “a source viewer”, as described above.

In regard to claim 14, Bassett et al. teach “a computer code for receiving a source dataset selection command from the user for identifying a source dataset corresponding to a subset of biological data being displayed on a source viewer, said source viewer being one of said plurality of viewers (column 2, lines 63-67)”.

In regard to claim 15, Bassett et al. teach “a dynamic menu information defining biological data field items, subcategory items, and submenuing relationships among said biological data field items and subcategory items (column 3, lines 32-35)”.

In regard to claims 16 and 61, Bassett et al. teach a relational database at column 1, lines 57-63).

In regard to claims 17 and 71, Bassett et al. teach analysis of cancer cells (column 40, line 59 and column 47, lines 26-41).

In regard to claim 19, Bassett et al. teach relational management (column 12, lines 8-27 and column 13, lines 8-27).

In regard to claims 20-22, Bassett et al. teach disease diagnosis and relating sequence information to clinical information (column 11, lines 29-37).

In regard to claim 23, the user device of Bassett et al. is a computer system.

In regard to claim 25, Bassett et al. teach a server with data storage (column 12, lines 49-62).

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In regard to claim 26, Bassett et al. teach a user interface module (column 15, lines 56-67).

Bassett et al. teach the limitations of claim 27 at column 16, lines 47-64.

The data can be patient information, as taught by Bassett et al. at column at column 11, lines 21-37). Biological samples yielding information about HIV etc. are inherently from patients (claims 20 and 63).

In regard to claims 29-31 and 66-68, Bassett et al. teach hierarchical clustering, other types of clustering, and statistical programs (column 3, lines 11-20; column 15, lines 56-67; and column 21, lines 1-67).

In regard to claims 32 and 69, Bassett et al. teach that perturbation of a sample by a drug candidate which yields information regarding upregulation or down regulation, which could be viewed as adverse effect or efficacy (column 8, lines 35-50).

In regard to claim 33, Bassett et al. teach “given one or more known successful drug targets, this technique allows the identification of new perspective drug targets involved in the same cellular pathway or process based on their positional relationship with known targets on the cluster tree (or distance metric between them) (column 23, lines 15-20)”.

In regard to claim 38, Bassett et al. teach non-human tissues (column 29, lines 15-27).

In regard to claim 39, Bassett et al. teach information relating to cell lines (column 10, lines 30-32).

In regard to claims 40, 41, and 70, Bassett et al. teach molecular profiling (entire patent) in a population of individuals (column 29, lines 15-27).

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In regard to claim 45, Bassett et al. teach the use of structured language query, a form of natural language querying (column 31, lines 13-35).

In regard to claim 65, Bassett et al. teach relating gene expression with the tissue on the microarray (column 12, lines 27-48).

In regard to claim 73, Bassett et al. teach that “the projections are characterized by a highlighted display of biological data points in the destination biological viewers corresponding to items in the source dataset (column 2, lines 8-13).

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 18 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,847,897 B1 (Bassett et al.) as applied to claim 6 and 7 above, and further in view of Moore et al. (Arch Pathol Lab Med (1996) Vol. 120(8), pages 782-785).



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As recited above, Bassett et al. teach a “system, method, and computer program product for improved computer-aided analysis of biological data derived from machine readable outputs of experiments performed on a plurality of biological samples (column 1, lines 66 and 67 to column 2, lines 1-2)”. In Figure 3, Bassett et al. describe a biological database software 302 which comprises a communications interface module 308, a biological information processing module 310, a database 312, and a SQL query processing/response module 314.

Communications interface module 308 coordinates data transfer between the database server 106 and the scanning device 104 for receiving biological response information (column 14, lines 61-67 to column 17, lines 64). Samples may consist of biological data from any multicellular organism (claim 37) (column 10, lines 31-34).

In regard to the “database searching function allowing the user to design queries, Bassett et al. teach “biological menu and submenu items that are displayed to the user during searches, projections, and the like are not stored in the user computer, rather are stored in a central response database”, thus meeting the limitation of querying information (column 2, lines 26-34).

In regard to “the relationship determination function”, Bassett et al. teach “computing a correlation metric between at least one of said plurality of biological signal profiles and other of said plurality of biological signal profiles in a central database server” (column 5, lines 9-12).

In regard to claim 7, which identifies sublocation, Bassett et al. disclose “a subset of biological data” at column 2, line 63.

Bassett et al. do not specifically teach an autopsy subdatabase or demographic information. However, Moore et al. teach an autopsy database available on the Internet, which comprises demographic and diagnostic information (see conclusions).

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It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have included the information from the autopsy database of Moore et al. in the information resources of the Bassett et al. invention. The motivation is provided by Bassett et al. at column 30, lines 25-31 and column 30 line 65 to column 31, line 13, who indicate that links may be used to connect to relevant biological resources that are related to a data elements. Specifically, one can assign a link to a gene or protein of interest in a database such as Entrez. Medline, or NCBI.

Claims 6, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,847,897 B1 (Bassett et al.) as applied to claim 6 above, and further in view of Bruijn et al. (Medical Informatics Europe '96, J. Brender et al. eds., pages 198-202).

As recited above, Bassett et al. teach a “system, method, and computer program product for improved computer-aided analysis of biological data derived from machine readable outputs of experiments performed on a plurality of biological samples (column 1, lines 66 and 67 to column 2, lines 1-2)”. In Figure 3, Bassett et al. describe a biological database software 302 which comprises a communications interface module 308, a biological information processing module 310, a database 312, and a SOL query processing/response module 314. Communications interface module 308 coordinates data transfer between the database server 106 and the scanning device 104 for receiving biological response information (column 14, lines 61-67 to column 17, lines 64). Samples may consist of biological data from any multicellular organism (claim 37) (column 10, lines 31-34).

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In regard to the “database searching function allowing the user to design queries, Bassett et al. teach “biological menu and submenu items that are displayed to the user during searches, projections, and the like are not stored in the user computer, rather are stored in a central response database”, thus meeting the limitation of querying information (column 2, lines 26-34).

In regard to “the relationship determination function”, Bassett et al. teach “computing a correlation metric between at least one of said plurality of biological signal profiles and one of said plurality of biological signal profiles in a central database server” (column 5, lines 9-12).

Bassett et al. do not specifically teach using SNOMED or natural language coding. However, Bruijn et al. teach the use of SNOMED and natural language for medical coding systems (abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time of invention to have used the codes in Bruijn et al. for coding the system of Bassett et al. Bassett et al. provide the motivation to utilize any computer code suitable for computer-aided analysis of response data, computer cluster analysis, computer query, computer statistics etc. at columns 2, line 59 to column 3, line 67.

Claims 6, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,847,897 B1 (Bassett et al.) as applied to claims 6 and 43 above, and further in view of Ahlberg (SIGMOD Record (1996) Vol. 25, No. 4, pages 25-29).

As recited above, Bassett et al. teach a “system, method, and computer program product for improved computer-aided analysis of biological data derived from machine readable outputs of experiments performed on a plurality of biological samples (column 1, lines 66 and 67 to

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column 2, lines 1-2)". In Figure 3, Bassett et al. describe a biological database software 302 which comprises a communications interface module 308, a biological information processing module 310, a database 312, and a SOL query processing/response module 314.

Communications interface module 308 coordinates data transfer between the database server 106 and the scanning device 104 for receiving biological response information (column 14, lines 61-67 to column 17, lines 64). Samples may consist of biological data from any multicellular organism (claim 37) (column 10, lines 31-34).

In regard to the "database searching function allowing the user to design queries, Bassett et al. teach "biological menu and submenu items that are displayed to the user during searches, projections, and the like are not stored in the user computer, rather are stored in a central response database", thus meeting the limitation of querying information (column 2, lines 26-34).

In regard to "the relationship determination function", Bassett et al. teach "computing a correlation metric between at least one of said plurality of biological signal profiles and other of said plurality of biological signal profiles in a central database server" (column 5, lines 9-12).

Bassett et al. do not teach the database manager specifically as that of Spotfire<sup>TM</sup>. However, Ahlberg does teach that Spotfire<sup>TM</sup> is a database exploration system based upon interactive information visualization, dynamic queries, brushing, and linking, and other interactive graphic techniques (abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used Spotfire<sup>TM</sup> of Ahlberg as the database manager in the system of Bassett et al. Bassett et al. provide the motivation to use any such database manager available at

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column 14, lines 1-12, which states that “a variety of references are publicly available for further information on implementing relational or object oriented databases”.

### **Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

The previous rejections under 35 USC 112, first paragraph have been withdrawn in view of Applicant's amendments.

The previous rejections under 35 USC 112, second paragraph have been withdrawn in view of Applicant's arguments and amendments.

The prior art of Kallioniemi et al. has been withdrawn in view of Applicant's amendments.

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**Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

May 12, 2005  
Lori A. Clow, Ph.D.  
Art Unit 1631  
*Lori A. Clow*

*Marjorie A. Moran*  
*5/12/05*  
**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**